IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	C.A. No. 18-823-CFC-JLH
v.	)	[redacted]
EAGLE PHARMACEUTICALS INC.,	)	
Defendant.	)	

DECLARATION OF MARK BRADLEY IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION PENDING APPEAL

Mark Bradley, of full age, hereby declares as follows:

1. I am the Executive Vice President and Chief Financial Officer for Endo International plc. In that role, I am responsible for providing leadership, direction and management of all financial activities for the company, including financial strategy, budgeting and forecasting, financial reporting, internal controls and compliance, and cash management and capital market activities. I make this declaration in support of Plaintiffs' Motion for a Preliminary Injunction Pending Appeal.

2. Endo International plc is a global specialty pharmaceutical company headquartered in Dublin, Ireland that conducts business through its operating

subsidiaries in four business segments: (1) Branded Pharmaceuticals, (2) Sterile Injectables, (3) Generic Pharmaceuticals, and (4) International Pharmaceuticals (collectively, with its operating subsidiaries "Endo"). Endo has a long-standing history of success in developing and delivering innovative and high-quality pharmaceutical products across a broad spectrum of therapeutic areas, including: emergency care, infectious disease, allergy immunotherapy, dermatology, orthopedics, endocrinology, and urology. Endo employs approximately three thousand employees around the world and had nearly $3 billion in total revenues in 2020.

3. Endo invests heavily in research and development (R&D) and continues to maintain a robust pipeline of potential new products across all of its segments. Endo's most recent and notable Branded pipeline success was QWO®, the first and only FDA-approved injectable treatment for moderate to severe cellulite in the buttocks of adult women. Additionally, Endo has two active clinical studies underway for Xiaflex focusing on the treatment of plantar fibromatosis and adhesive capsulitis. These product candidates represent opportunities to bring innovative treatment options to address potentially large unmet needs for patients who are seeking non-surgical approaches to treatment. Endo is also committed to expanding its R&D pipeline and manufacturing capabilities to support the introduction of more sterile injectable products that

focus on the evolving needs of its customers. Endo has approximately 40 R&D projects in its pipeline. Over 85% of the R&D pipeline consists of projects across the sterile injectable product continuum, with approximately two-thirds in ready-to-use and other more differentiated products.

4. Plaintiff Par Sterile Products, LLC ("Par Sterile") is the Sterile Injectables segment of Par Pharmaceutical, Inc., Endo's wholly-owned generic pharmaceutical subsidiary ("Par Pharmaceutical"). Par Sterile develops, manufactures, and markets branded and generic sterile injectable products, and currently markets a portfolio of 37 specialty injectable products. Par Sterile was formed in 2014, when Par acquired JHP Pharmaceuticals ("JHP"), to expand Par's presence into the market for sterile injectables. Par Sterile provides hard-to-manufacture, life-saving injectable products, including Vasostrict®.

Market for Vasopressin Products/Vasostrict®

5. Vasostrict® is a life-saving injectable drug product primarily used by hospitals in emergency situations to treat, among other things, dangerously low blood pressure for patients in septic shock and post-cardiotomy shock. The active ingredient is vasopressin, which is a peptide drug that quickly increases a patient's blood pressure by causing blood vessels to contract. Vasostrict, which is currently sold in the form of 1 mL and 10 mL vials, is typically administered by withdrawing the desired amount of vasopressin into a syringe, diluting by injecting

it into an IV bag, and then intravenously administering it to the patient via an IV drip.

6. Vasostrict is made and sold through plaintiffs Par Pharmaceutical, Par Sterile, and Endo Par Innovation Company, LLC, each of which is a wholly-owned subsidiary of Endo as noted above (collectively, "Par"). Endo and Par view the Sterile Injectables segment, which includes Vasostrict, as a core business and growth area that is vital to the sustained success of the entire company.

7. Currently, Vasostrict is Endo's largest and one of its most profitable products. Specifically, Vasostrict is expected to generate revenues of almost [redacted] or nearly [redacted] of Endo's company-wide revenue in 2021. However, Vasostrict is expected to account for more than [redacted] of Endo's company-wide EBITDA[1] in 2021. The profits generated from the sales of Vasostrict are critical to Endo's ability to fund and support its and Par's overall business operations,

[1] "EBITDA" is an acronym for a company's earnings before interest, taxes, depreciation, and amortization. It provides a reflection of a company's operating profitability and is an important metric used by many analysts and investors when conducting financial analyses to determine a company's value.

[redacted]

including its continued investments in Branded and Sterile injectable R&D which is an important driver of future revenue growth for Endo and Par; Endo's and Par's investments in sales and marketing of their product portfolios, including the investments necessary to successfully launch new products, [redacted] and to support the projected growth of existing products, [redacted] the payment of employee salaries and other general and administrative expenses necessary to sustain the day-to-day operations of the companies; the funding of legal expenses related to the defense and resolution of numerous opioid and other contingent liabilities; and the payment of significant interest and principal on Endo's outstanding debt obligations that total over $8 billion.

8. Vasopressin products were sold for many years as an unapproved drug. Par (and its predecessor JHP) invested millions of dollars in developing and obtaining FDA approval for Vasostrict, and Par has continued to invest heavily in further improvements to the product, which has included development of a reformulated, more stable vial product and innovative ready-to-use bottles and bags. Vasostrict was first approved in April 2014, and through significant additional R&D, Par successfully developed and obtained approval for a reformulated version of Vasostrict with enhanced stability as compared to the original version. The U.S. Patent Office granted multiple patents to Par based on

its development work that are listed in the FDA's "Orange Book" with respect to that product.

9. In addition, more recently, Par has successfully developed and obtained approval for premixed, ready-to-use bottle products in three dosage strengths (20 units/100mL (0.2 units/mL), 40 units/100 mL (0.4 units/mL), and 60 units/100 mL (0.6 units/mL)). These bottle products need not be diluted prior to administration, which will provide advantages in ease and speed of use for the nurses and other medical professionals who administer the products to patients. Par also obtained additional patents covering these products, which are listed in the FDA's "Orange Book" with respect to them.

10. Currently, Par is the only company that markets an FDA-approved vasopressin product, and thus, Par has 100% of the vasopressin market. At all times, Par has been able to safely and reliably supply vasopressin products sufficient to satisfy the market demand for this important drug. Par has never experienced a shortage of supply for any of its Vasostrict customers. Vasopressin vials are not included on the FDA's drug shortage list[2] and Endo anticipates that Par will be able to continue to supply the entire market for the foreseeable future.

[2] *See* https://www.accessdata.fda.gov/scripts/drugshortages/.

11. Par sells Vasostrict primarily to group purchasing organizations ("GPOs"), which negotiate and purchase products in aggregate on behalf of member hospitals and other acute care clinics/facilities that administer the products to patients. There are three large GPOs—HPG, Premier, and Vizient—that collectively comprise approximately [redacted] of the market for Vasostrict. The remaining [redacted] of the market is comprised of other small hospitals and compounders. Compounders buy Vasostrict vials and convert them in into IV bags for hospital usage.

Generic Competition for Vasostrict

12. Eight generic pharmaceutical companies have submitted applications for approval to market generic versions of Vasostrict in accordance with the Hatch-Waxman Act—seven filed abbreviated new drug applications ("ANDAs") (Amneal, Amphastar, Aurobindo, Dr. Reddy's Eagle, Fresenius, and Sandoz) and one filed a Section 505(b)(2) new drug application ("505(b)(2) NDA") (American Regent), in each instance identifying Vasostrict as the reference-listed drug.

13. Par filed patent infringement actions against all eight of these generic filers. Par has successfully negotiated settlements with six of the eight—all but Amneal and Eagle. Pursuant to each settlement, [redacted]

[redacted]

14. The FDA has just approved Eagle's ANDA,[3] and Eagle's Chief Executive Officer has made repeated public statements that Eagle intends to launch its generic vasopressin product ("Eagle's ANDA Product") promptly after receiving such an approval. This would be a launch "at risk" because (a) it would not be authorized by Par and (b) the appeals court has yet to resolve Par's pending appeal of this Court's non-infringement ruling.

15. The FDA previously approved American Regent's 505(b)(2) NDA, on August 3, 2020. [redacted]

16. The FDA has yet to approve any of the other generic filers' ANDAs. [redacted]

[3] A copy of a press release from Eagle confirming the FDA's approval of its ANDA is attached hereto as Exhibit A.

[redacted]

Impact of Generic Competition for Vasostrict

19. As noted above, one of Endo's four principal business segments is Generic Pharmaceuticals, which is conducted through Par and other Endo subsidiaries. As a result, Endo and Par have extensive knowledge of and experience related to the impact that the introduction of generic competition can have on the market for pharmaceutical drug products. Endo regularly incorporates that knowledge and experience into its business plans and forecasts for the portfolio of new and existing drug products sold by its subsidiaries, including with respect to Par's Vasostrict product.

20. Consistent therewith, Endo's business plan and projections for the Vasostrict franchise have incorporated the likely impact of a potential launch-at-risk by a generic manufacturer (such as Eagle) [redacted] Endo's current financial projections for the Vasostrict franchise are set forth, for instance, [redacted]

21. In particular, based on its extensive knowledge and experience with generic products and sterile injectable products (like Vasostrict), and taking into account the particular dynamics of the market for vasopressin (including, for instance, the need for such products, the projected interchangeable use of any generic vasopressin products, and [redacted] Endo is projecting for internal planning purposes that a generic launch-at-risk (like the one planned by Eagle), if left unchecked, will have the following impacts on Endo's Vasostrict franchise and the company as a whole. While Endo has projected a variety of harms to Endo and Par that will be caused by any launch-at-

risk, there may be other forms of harm caused by any such at-risk launch, and the full extent of the harm (both those described herein and those that are yet to be identified) cannot be fully quantified with a reasonable degree of certainty.

Lost Market Share and Unrecoverable Loss of Vasostrict Revenues

22. Based on prior experience and recent analogues, Endo projects that the price for vasopressin products will drop by approximately [redacted] within the first quarter after any launch-at-risk and will further drop to lower than [redacted] of current levels within the first year. [redacted] Accordingly, Endo expects Par will have no choice but to respond by matching the generics' prices in order to retain any share of the market. The drop in price will likely be irrecoverable, even if Eagle were to be forced off the market following Par's appeal of the Court's non-infringement ruling, because we expect that an immediate return to the prior, higher price for the product would be unacceptable to the GPOs and other customers and would result in significant damage to Endo's and Par's goodwill with their customers. [redacted]

23. [redacted]

[redacted]

[redacted]

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4 [redacted]

[redacted]

26. Endo and Par further project that Par may be able to successfully retain [redacted] by continuing to also sell its existing Vasostrict vial products. However, for the reasons noted above, in order to retain any such market share, Par will have to drop the price of its vials to match that of the lowest-priced generic competitor.

27. Collectively, this would mean that, at best, Par may retain up to [redacted] of the market volume [redacted] However, the unit price would be [redacted] the price at which Par currently sells its Vasostrict vials. Consequently, while Par may be able to retain up to [redacted] market share, the precipitous drop in unit price would result in a significant loss of revenues from an unchecked launch-at-risk.

28. Specifically, Endo and Par project that the quarterly revenues generated by their Vasostrict franchise will drop by approximately [redacted] in the first quarter after a launch-at-risk (from approximately [redacted] per quarter to approximately [redacted]. The total loss in annual revenues after a launch-at-risk is projected to be approximately [redacted] within the first year. For the reasons noted above, Endo and Par project that revenues would not return to

current levels even if Eagle launched but was then forced to withdraw from the market following Par's appeal of the Court's non-infringement ruling. [redacted]

29. The projected drop in annual revenues of approximately [redacted] would represent an approximate [redacted] drop in Endo's company-wide revenues and result in an approximately [redacted] drop in Endo's company-wide EBITDA. A precipitous drop in revenue and EBITDA of that magnitude would have wide-ranging impacts on Endo and its various other business segments above (including those operated by Par) and beyond just the impact on its Vasostrict franchise, including at least the following impacts.

Lost Investment in R&D

30. Endo invests more than $100 million annually in research and development of new and improved drug therapies, and that R&D is the engine that has led to the successful development and launch of numerous new and improved drug products by Par and other Endo subsidiaries that are improving the lives of millions of patients all around the world.

31. Since Vasostrict accounts for more than [redacted] of Endo's company-wide EBITDA, it follows that [redacted] of investments in R&D are effectively funded by Vasostrict. Accordingly, a precipitous drop of [redacted]

in annual Vasostrict revenues and corresponding reduction in EBITDA would significantly impair Endo's ability to continue to invest in future R&D efforts at its current levels, including in particular its planned investments in R&D by Par. The company's product development pipeline, which is supported by its investments in R&D, is an important driver of the Endo's and Par's future revenue and growth potential. The lost opportunities to Par and Endo resulting from a reduction in R&D would have ripple effects that extend long into the future. Given the unpredictable nature of pharmaceutical drug product development, the ultimate magnitude of those ripple effects is unknowable and incalculable.

Impaired Ability to Support New Product Launches and the Growth of Existing Product Franchises

32. Vasostrict is an established product that is well-known and well-understood in the marketplace. Therefore, Vasostrict requires minimal investment in sales and marketing. However, [redacted] As with Endo's investments in R&D, [redacted] of the company's investment in sales and marketing is effectively being funded by the profits generated from the Vasostrict franchise. Thus, a precipitous drop in annual Vasostrict revenues and corresponding EBITDA would significantly impair Endo's ability to invest in sales and marketing activities to

support its other products, including other products sold by Par, which would have wide-ranging impacts far beyond the Vasostrict franchise.

33. Sufficient investment in sales and marketing is critical to support new product launches, [redacted], and the growth of other product franchises, [redacted]. When a pharmaceutical company initially launches a new drug product, it must invest significant up-front time and money to educate consumers and the medical community about the benefits of the new product. The inability to adequately invest in such education and other marketing efforts can dramatically affect the rate at which a product is adopted and used by physicians and the accompanying revenue growth trajectory for the product.

34. For Endo, the inability to fund planned investments in sales and marketing would negatively impact the projected revenues from [redacted] And the lost revenue opportunities resulting from a sub-optimal launch would be irreversible, because once the momentum for a new product launch is lost, it can never be re-gained, and the lost revenue growth cannot be recovered. A reduction in sales and marketing would also negatively impact [redacted] as promotional efforts continue to drive growth and awareness of the condition, treatment options and the product. The loss of anticipated revenues [redacted] would have further future effects on

both Endo and Par, compounding the impacts discussed herein that would result from a drop in Vasostrict revenues and associated EBITDA (e.g., further impairing Endo's ability to fund R&D, to support additional new product launches, etc. for Par and its other subsidiaries).

35. As with the impact of lost R&D, the full extent of the decreased revenues and other ripple effects of business opportunities lost by Par and other Endo subsidiaries as a result of Endo's impaired ability to fund its planned sales and marketing efforts for [redacted] new and early-stage products is unknowable and incalculable with any degree of certainty.

Impairment of Ability to Pay Employee Salaries and Other G&A Impacts

36. A precipitous drop in annual Vasostrict revenues and associated EBITDA resulting from an unstopped generic launch-at-risk would also significantly impair Endo's ability to fund its general and administrative expenses, including for example the salaries of its corporate and administrative employees (over and above the loss of highly-skilled scientific and technical personnel resulting from the above-described reduction in R&D investments and the potential loss of sales and marketing personnel resulting from the above-described reduction in sales and marketing investments), real estate and office expenses, and other overhead expenses incurred by Endo, Par, and Endo's other subsidiaries. Thus, if the Court does not enjoin Eagle from proceeding with its planned at-risk launch

pending appeal, Endo would have to either incur significant additional debt (or delay debt repayments) to continue to fund these expenses at current levels (which may not be possible and would be problematic in any event for the reasons discussed below) or reduce those expenses by cutting staff, cutting real estate (offices, laboratories, production facilities, warehouses, etc.), and/or other overhead expenses of Par and other subsidiaries.

Impaired Ability to Defend and Resolve Opioid and Other Contingent Liabilities

37. Although it no longer promotes any opioid products, Endo is a defendant, along with numerous other manufacturers and distributors of opioid pain medications, in more than 3,000 lawsuits across the country that have been filed by state attorneys general and local governments, private payers, and individuals. Endo has settled several cases, with no admission of liability, including an $11 million settlement with two counties in Ohio;[5] an $8.75 million settlement with the State of Oklahoma;[6] a $35 million settlement of a Tennessee lawsuit filed by nine counties in eastern Tennessee, eighteen cities and towns

[5] https://investor.endo.com/news-releases/news-release-details/endo-announces-execution-final-settlement-agreement-and-release

[6] https://investor.endo.com/news-releases/news-release-details/endo-settles-opioid-investigation-state-oklahoma-875-million.

within those counties and one individual plaintiff;[7] a $50 million settlement with the State of New York and two New York counties;[8] and a $7.5 million settlement with the state of Louisiana.[8]

38. [redacted] The profits generated from Vasostrict help to fund the costs associated with the opioid litigation and other contingent liabilities. Consequently, a precipitous drop in Vasostrict revenues and associated EBITDA would impair Endo's ability to continue to defend itself, fund future settlements with additional plaintiffs, and/or pay any judgments that might be entered against it. That impairment would, in turn, further impact Par and Endo's other subsidiaries in ways that are unknowable and incalculable with precision in advance.

Impaired Ability to Pay Down Debt / Increased Cost of Capital

39. Endo is a highly-levered company, with more than $8 billion in debt. As a result, Endo needs to generate sufficient cash flow to not only support the

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[7] https://investor.endo.com/news-releases/news-release-details/endo-announces-agreement-principle-settle-tennessee-state-court.

[8] https://investor.endo.com/news-releases/news-release-details/endo-settles-new-york-state-opioid-cases-and-provides-update

[8] https://investor.endo.com/news-releases/news-release-details/endo-reaches-agreement-principle-settle-louisiana-governmental

company's ongoing operational expenses (such as those described above), but also satisfy its debt obligations (interest and principal payments) as they become due. As with its other expenses, the profits generated from Vasostrict account for a substantial portion of the cash flows that Endo uses to meet those debt obligations. Consequently, a precipitous drop in Vasostrict revenues and associated EBITDA would negatively affect Endo's ability to both fund its planned operations and meet its ongoing debt obligations.

40. Moreover, the projected drop in revenues would increase Endo's cost of capital and make it more difficult and more expensive for Endo or Par to incur future debt to support their operations. Indeed, both S&P Global and Moody's have already downgraded Endo's corporate credit rating to CCC+ and Caa1, respectively, citing this Court's non-infringement ruling in favor of Eagle in this action as one of the primary reasons for doing so.[9] These ratings suggest that Endo is vulnerable to default which will make it more difficult and more expensive for Endo or Par to obtain needed credit in the future. In fact, many suppliers and vendors are already seeking more favorable payment terms (or prepayment of expenses) from Endo as a result of the downgrade in Endo's corporate credit ratings.

[9] *See* Exs. C and D hereto.

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41. In summary, if Eagle were permitted to proceed with its planned launch-at-risk unchecked, that launch would have wide-ranging, multi-faceted, long-term effects not only on the Vasostrict franchise but also on the company as a whole, including on Par and Endo's other operating subsidiaries. The impacts on Endo's and Par's investments in R&D and planned sales and marketing efforts, on Endo's and Par's ability to fund employee salaries and other overhead expenses, on Endo's ability to defend and resolve the ongoing opioid litigation and other contingent liabilities, and on Endo's ability to pay interest and principal on outstanding debt are all inter-related and intertwined. A negative impact in any one of these areas would necessarily have compounding ripple effects that negatively affect the others. As noted above, the full extent of these ripple effects would be both incalculable and irreversible.

42. Indeed, if Eagle were permitted to proceed with its planned launch-at-risk, the collective impact of the severe harms described above would seriously threaten Par's and Endo's business and potentially impair their ability to continue as a going concern. As noted above, Endo has a significant amount of outstanding debt (over $8 billion) and pays over $550 million per year in interest, or approximately 20 percent of its total annual net revenues, to its debt holders. The debt is accompanied by various covenants that restrict Endo's operations, including

by imposing limits on the company's ability to pursue new acquisitions, to sell assets, and to incur additional debt, [redacted] As a result, any launch-at-risk by Eagle would raise substantial doubt about Endo's and Par's ability to continue as going concerns, as reflected in the downgrades in Endo's credit ratings described above.

43. As Endo stated in its most recent Form 10-Q quarterly SEC filing:

> We rely on cash from operations as well as access to the financial markets to fund our operations, maintain liquidity and meet our financial obligations. Our operations are subject to many significant risks and uncertainties, including those related to generic competition and legal challenges that could impact our key products, including VASOSTRICT®, outstanding and future legal proceedings and governmental investigations, including those related to our sale, marketing and/or distribution of prescription opioid medications, and others. Any negative development or outcome in connection with any or all of these risks and uncertainties could result in significant consequences, including one or more of the following:
>
> - causing a substantial portion of our cash flows from operations to be dedicated to the payment of legal or related expenses and therefore unavailable for other purposes, including the payment of principal and interest on our indebtedness, our operations, capital expenditures and future business opportunities;
> - limiting our ability to adjust to changing market conditions, causing us to be more vulnerable to periods of negative or slow growth in the general economy or in our business, causing us to be unable to carry out capital spending that is important to our growth and placing us at a competitive disadvantage;
> - limiting our ability to attract and retain key personnel;
> - causing us to be unable to maintain compliance with or making it more difficult for us to satisfy our financial obligations under certain of our outstanding debt obligations, causing a downgrade of our debt

and long-term corporate ratings (which could increase our cost of capital) and exposing us to potential events of default (if not cured or waived) under financial and operating covenants contained in our or our subsidiaries' outstanding indebtedness;

- limiting our ability to incur additional borrowings under the covenants in our then-existing facilities or to obtain additional debt or equity financing for working capital, capital expenditures, business development, debt service requirements, acquisitions or general corporate or other purposes, or to refinance our indebtedness; and/or
- causing a significant reduction in our short-term and long-term revenues and/or otherwise causing us to be unable to fund our operations and liquidity needs, such as future capital expenditures and payment of our indebtedness.

Endo International plc Form 10-Q (dated August 2021) at 51.

44. For all of these reasons, the financial harm that Endo and Par would suffer in the event of an unchecked launch-at-risk by Eagle would be considerable, to the point of raising substantial doubt about the ability of Endo and Par to continue as going concerns and potentially triggering a bankruptcy filing.

I declare, under the penalty of perjury, that the foregoing statements made by me are true to the best of my knowledge, information and belief.

Dated: December 16, 2021

Mark Bradley